RECOMMENDATIONS ON THE USE OF POTASSIUM IODIDE AS A THYROID-BLOCKING AGENT IN RADIATION ACCIDENTS: AN FDA UPDATE*

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THE Food and Drug Administration published a notice in the *Federal Register* on December 15, 1978 entitled "Potassium Iodide as a Thyroid Blocking Agent in a Radiation Emergency." In this notice, the F.D.A. invited manufacturers to submit New Drug Applications for potassium iodide products and announced the availability of labeling guidelines. The notice had no immediate effect, however, on public discourse.[1] It was only after the accident at Three Mile Island that the F.D.A. received any new drug applications. Approval of these applications opened further debate about the use of potassium iodide. The past three years have produced vigorous, often heated discussion about the role of the drug as a thyroid-blocking agent. Many opinions were expressed about the population for whom the drug should be used, the thyroid dose, and methods to make it available. The controversy did not reach its heights until the F.D.A. issued its final recommendations on the use of potassium iodide as a thyroid-blocking agent in a radiation emergency.[2] This is not surprising because the agency had to make some decisions with which there was no unanimity. These decisions involved weighing the benefits of using potassium iodide with the radiation risks to the thyroid gland of ^{131}I. There are, in addition, other controversial matters concerning the stockpiling and distribution of potassium iodide on which the F.D.A. properly took no position is because these matters do not fall within its jurisdiction. At this juncture it is appropriate to review the F.D.A.'s recommendations to understand its positions and the likely implications for the use of potassium iodide. At the same time, it is also appropriate to review the related issues upon which the F.D.A. did not take a position.

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Safety and Effectiveness

In its initial notice on potassium iodide, the F.D.A. stated that potassium iodide is a safe and effective thyroid-blocking agent in a radiation emergency in which radioiodines are accidentally released into the environment.[1] This finding is based on review of information on the ability of stable iodine to saturate the thyroid gland and on possible side effects of the drug in the published literature dating back to the 1800s, including reports in the F.D.A.'s Voluntary Reporting System on adverse drug reactions.

There is general agreement that the drug can achieve almost complete (greater than 90%) blocking of radioactive iodine uptake by the thyroid gland. This effect can be obtained by the oral administration of 130 mg of potassium iodide (65 mg for infants under one year of age) just before or at the time of exposure to iodine-131. A substantial benefit (i.e., a block of 50%) is attainable if administered up to three to four hours after acute exposure.

On the issue of potassium iodide's safety, however, there is less agreement. For example, Dr. Yalow raised significant questions concerning the risk of potassium iodide in her comments on a draft of the agency's recommendations[3] and, more recently, in a summary of testimony at a Congressional hearing chaired by Mr. Markey of Massachusetts held on March 5, 1982.[4] Dr. Yalow suggested that, based on experience by Curd[5] and the incidence of hypocomplementemic vasculitis in rheumatoid arthritis, there might be six in 10,000 acute severe reactions from medically unsupervised administration of potassium iodide. In Curtis' study, metabolic studies of radio-labeled proteins were conducted in 126 patients of which four (3% of the patients in the study group) were suspected of being sensitive to potassium iodide because they had repeatedly developed urticaria and other allergic symptoms after multiple administrations. The potassium iodide was administered in 0.5 gram doses on multiple occasions in serial fashion to block thyroid uptake of iodine for purposes of the study. Two of the four patients were selected to evaluate the possible association of potassium iodide sensitivity with urticaria, hypocomplementemia, and vasculitis. The patients were given 1 gm of potassium iodide initally and then potassim iodide was administered twice a day until sensitivity reactions occurred or for two days. Challenge with 1 gm of potassium iodide in the two sensitive patients precipitated an allergic reaction of moderate severity in one patient and a prolonged

severe systemic illness in the other. The authors believed both reactions were caused by the potassium iodide. Ten control patients did not present the same reaction, tending to confirm the diagnosis of potassium iodide sensitivity in the two patients.

Thus, Curd's study confirmed potassium iodide sensitivity in two patients who had had repeated, multiple, large (0.5 gm) administrations of the drug.

Hypocomplementemic vasculitis is rare. At the University of Cincinnati Medical Center, a referral institution with more than 2,000 patient beds and hundreds of thousands of outpatient visits per year, only 12 individuals are seen per year with this condition.[6] Based on Curd's study,[5] in which 3% of the patients had a severe reaction and the incidence cited above, the figure of six per 10,000 appears to be greatly overestimated.

Potassium iodide in large doses (300 to 1,200 mg daily for adults and 100 mg or more for children) has been widely used for years in the long-term management of bronchial asthma and other pulmonary disorders. Individual medical literature reports of complications from iodide administration for the most part do not identify the size of the patient population taking iodides from which the cases have been drawn. While cases are undoubtedly under-reported, the number of reports of adverse reactions from potassium iodide received by the F.D.A. has been low. The incidence of significant adverse reactions from short-term administration of potassium iodide to humans in daily doses of 65 or 130 mg is unknown but is expected to be low.[2] (It is important to distinguish the much more common reports of reactions to organic bound iodine compounds.)

The known potential for potassium iodide to cause serious side effects in a small sensitive population is not sufficient grounds from which to conclude, or even to suggest, a significant and quantifiable proportion of serious reactions or deaths in patient populations which would be exposed to much smaller doses of the drug over a limited time and which would not be expected to include patients of this category.

Adverse reactions to potassium iodide can be grouped into thyroid and nonthyroid effects. For example, thyroid reactions include: iodide goiter with or without hypothyroidism (especially neonatal goiter), hyperthyroidism, and hypothyroidism. Nonthyroid reactions include: dermatologic and mucous membrane reactions, "Iodide Mumps" and miscellaneous reactions, and serum sickness type hypersensitivity and vascular reactions. The occurrence of most side effects and toxicities appears to be proportional to dose and duration of treatment, and, except for anaphylaxis, most

are not expected with the dose recommended for thyroid-blocking.

In view of the benefit to be derived from the use of the drug to block the thyroid in a radiation accident, the F.D.A. concluded that the benefit/risk ratio favors use of the drug for that purpose when the projected radiation dose to the thyroid gland from radioiodines released into the environment equals or exceeds 25 rem.

Thyroid Radiation Risks

There are few human data relevant to the induction of radiation effects from iodine-131, particularly in children. Two epidemiological studies attempt to quantify the risk of thyroid cancer from iodine-131 irradiation. Rallison et al.[7] and Holm[8] found no increase of thyroid cancer in their irradiated populations with estimated mean thyroid doses of 18 to 160 rem, respectively, from nuclear weapon fallout or iodine-131 diagnostic procedures when compared to the spontaneous thyroid cancer incidence. Holm's population was mostly adult at the time of irradiation.[8] Adult thyroid cells do not normally undergo cell division and their radiogenic thyroid cancer risk would not be expected to be the same as those in infants and children. Further, about a third of Holm's irradiated population[8] received thyroid hormone therapy, surgery, or both following irradiation, which may also have continued to the low observed thyroid cancer incidence.

In the Rallison et al. study, an estimated average thyroid dose of 18 rem from fallout from atmospheric nuclear weapon tests was believed to have been received by his study population.[7] Actual thyroid doses have not been adequately determined in this population, as evidenced by continuing controversy surrounding radiation effects near the Nevada test site from weapon testing in the 1950s and 1960s. Moreover, the follow-up period of 14 years in his irradiated population may not be adequate for full radiogenic thyroid cancer expression.

In an earlier case study of Marshall Islanders exposed to nuclear weapon fallout, Conard et al. found that within 22 years after exposure 24 of 68 people exposed on Rongelap had thyroid nodules and four of these were thyroid cancer.[9] Thyroid doses for the Rongelap people were estimated to be from 220 to 450 rads for an adult and 700 to 1,400 rads for a child.[9] These doses include those from radioiodines (including short-lived radioiodine isotopes) and an estimated external gamma dose of 175 rad.

The risk of thyroid cancer in man from external x rays has been

demonstrated in numerous epidemiologic studies.[10-12] For young adults treated with x rays, the risk of thyroid cancer is estimated at 1.6 to 9.3 excess cases of thyroid cancer per 10^6 PY-rem.[13] (PY is a person-year of follow-up.) Ron and Modan found increased thyroid cancers at a mean thyroid dose of about 9 rads in about 11,000 children irradiated for tinea capitis and followed for 12 to 23 years.[10]

The impression that iodine-131 is not as effective as x rays in thyroid cancer induction was based mainly on the observations of Doniach in rats and Maxon et al. in man.[14,15] Doniach's conclusion that x ray was 10 times more effective than iodine-131 in thyroid cancer induction was based on results of three rat studies in which an estimated thyroid dose of approximately 10,000 rem from iodine-131 was thought to be equivalent to that of 1000 rem from external x rays. In these studies a surviving proportion of less than 28% of the animals was left after a 15-month or a two-year study. Such low survival and small number of animals per dose group can lead to serious biases in the estimation of cancer incidence. The effect of cell killing at the high radiation doses due to the iodine-131 versus the lower dose used for external x rays was not explained by the Doniach study.[14] Similarily, the relative thyroid cancer susceptibility of 70:1 between x ray and iodine-131, as reported by Maxon et al. in children, could also be due to difference in cell killing at the higher iodine-131 doses used in the comparison. (The x-ray dose ranged from 0 to 1,500 rem, whereas the iodine-131 doses were approximately 9,000 rem.)

Thus, the risk of thyroid cancer following external x irradiation of the thyroid is well established, but the risks from internal exposure to iodine-131 are not. Until now the impression was that iodine-131 was much less effective than external x rays in thyroid cancer induction. The rationale usually given for this difference is a low dose rate and an uneven dose distribution in the thyroid gland from internal exposure to iodine-131. However, data from a recent animal study by Lee et al.[16] demonstrated that the dose-response functions in thyroid cancer induction in rats from both iodine-131 and external x rays are similar within the dose range of 0 to 1,000 rem.

The paucity of human data relevant to the induction of radiation effects from iodine-131, particularly in children, has convinced the F.D.A. that it is prudent to employ risk estimates from external irradiation studies in reaching the conclusions upon which its recommendations are based.

From this evidence, the F.D.A. concluded that the risks of radioiodine-

induced thyroid nodules or cancer at a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment outweigh the risks of short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency. The F.D.A. recommends that potassium iodide in doses of 130 mg per day for adults and children one year and above and 65 mg per day for children below one year of age be considered for those likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released to the environment.[2] A projected dose of this magnitude is equal numerically to the Environmental Protection Agency's upper Protective Action Guidance* level for the general public[17] and the United Kingdom's National Radiation Protection Board's upper level proposed for potassium iodide use.[18] These agencies expect some protective action to be taken at a projected radiation dose of 25 rem or greater to the thyroid from radioiodines released into the environment.

In its comments on a draft of the F.D.A.'s final recommendations, the American Thyroid Association wrote, "Based upon available data, it would seem unlikely that clinically significant thyroid disease would result from individual thyroid exposure of less than 100 rads. To provide an added measure of protection for children and pregnant women, a radiation dose of 50 rads to the thyroid is suggested as a threshold for iodine blockade for this group.[19]" This comment was made before the publication of the results of the animal studies of Lee et al.[16] and is thus based on earlier studies of comparative iodine-131 and external x-ray thyroid risks. In any case, given that the most sensitive segments of the population should be protected, the opinion of the American Thyroid Association and the conclusions of the F.D.A. are not very far apart.

Over-the-Counter Status

F.D.A. approved potassium iodide for use in radiation emergencies as a nonprescription drug because the agency concluded that adequate directions for its use by the public could be written.[1] A second reason for the decision was to provide the necessary flexibility to state and local officials considering distribution of potassium iodide as part of their emergency response planning.

*E.P.A. Protective Action Guides call for sheltering, evacuation, and controlled access as protective actions when the total accumulated thyroid doses are projected at 5 to 25 rem for the general population.[17] The lower level is used if there are no major constraints. If local constraints exist, the higher value is employed. However, the E.P.A. guides do not specifically note the use of potassium iodide as an appropriate protective action for the general population.

Even so, potassium iodide for thyroid blocking is unlike other nonprescription drugs: Its safe and effective use depends on a determination by local public health authorities that a radiation emergency has occurred or is likely and that projected release levels of radioiodines would make the benefits of using of the drug outweigh its risks. For that reason, special labeling for the consumer must accompany the drug. This labeling states, among other things, that it should be taken only when public health authorities so direct.

To date three manufacturers hold approved new drug applications for this product: Carter-Wallace, Roxane Laboratories, and Anbex, Inc. of New York City. In November 1982 Anbex, Inc. began newspaper advertisements in the Harrisburg, Pennsylvania, area, the site of the Three Mile Island plant, offering to sell potassium iodide tablets for radiation protection directly to the public. In press reports by the Associated Press and Harrisburg area newspapers, Anbex said it also planned to promote the tablets soon in Peoria, Ill.—a city not near a nuclear power plant—to compare public response with that of the Harrisburg area. If interest was strong, a nationwide marketing campaign by Anbex was planned.

While the other F.D.A.-approved manufacturers of potassium iodide for thyroid blocking (Carter-Wallace and Roxane Laboratories) voluntarily agreed at the time of approval to limit distribution to state and local officials and nuclear power plant operators, Anbex did not agree to such restrictions. Because of Anbex's campaign, the F.D.A. notified these other manufacturers that it no longer expects them to abide by their voluntary agreements.

Although potassium iodide is also available as an ingredient in prescription drugs to treat asthma and other lung disorders, these prescription products provide much higher doses than are necessary for thyroid blocking in a radiation emergency, and the enteric coated form of many of these delays absorption through the digestive tract, possibly impeding the drug's effectiveness in radiation emergency. Further, prescription products are not labeled properly for this specific use.

Distribution, Stockpiling, And Cost Effectiveness

Perhaps the most heated aspects of the controversy surrounding the use of potassium iodide are stockpiling, distribution, and cost effectiveness. The Department of Health and Human Services (and hence the F.D.A.) is charged with providing guidance to state and local governments on the use

of potassium iodide, including the radiation dose at which its use should be considered. The Department's role is not to define whether or not potassium iodide should be stockpiled or distributed. These responsibilities properly reside with the states. Federal guidance in these matters, however, is to be provided by the Federal Emergency Management Agency and the Nuclear Regulatory Commission, not the F.D.A.[20]

On these matters the F.D.A.'s final recommendations state:

> Each State has the responsibility for formulating guidance to define if and when the public should be given potassium iodide and instructed to use it. In preparing guidance and making rules, State or local officials should inform citizens of the nature of the radiation hazard and of the potential benefits and adverse effects of potassium iodide. In those instances where State or local officials administer or direct the administration of the drug to citizens the same kinds of issues as to liability may arise as have arisen in public immunization programs.[21,22] Citizens should be provided with, and encouraged to read, the information leaflet, which accompanies the drug. Notice of the availability of guidelines on the information leaflet has been published in the *Federal Register*.[1,23]

Also, the Department and the F.D.A. recently approved a draft of the Federal Radiological Preparedness Coordinating Committee's national policy statement that reiterated this stand.[24]

Once it is determined to include potassium iodide in emergency plans, the two issues regarding supply are: stockpile or don't stockpile and, if the decision is made to stockpile, then predistribute or don't predistribute. Advocates of stockpiling say that proper preparedness planning requires that an adequate amount of potassium iodide tablets or solution be available within the state or, where there is more than one nuclear power plant, at several sites within the state. From these sites, in the event of an emergency, it can be rapidly distributed to those living where they may risk doses to the thyroid of 25 rem or greater. Nonstockpile advocates point out that stockpiling is expensive. It requires the initial purchase of the drug plus warehouse expenses. Since drug products have finite lifetimes, replacement of stockpile stocks when the drug product reaches its expiration date would require additional investment. Nonstockpile advocates argue that, in the event of an emergency, the drug can be procured quickly from the manufacturer or, conversely, the drug should be stockpiled, but by the federal government or the utility, not by the state.

The case for predistribution is based upon the premise that if and when the drug is needed, it would take too long for it to reach the affected population for large stockpile locations and, to be sure that people will have it when they need it, each person, family, or household should have

its own supply readily available. Such predistribution to the household level would solve one logistics problem, but, as those who oppose predistribution argue, it would substitute a different set of problems. They point out that if the drug were predistributed to households it would likely get lost or be forgotten when the emergency was at hand or it could be out of date.

According to information from the Conference of Radiation Control Program Directors, state emergency plans have addressed these supply issues in the following manner.[25]

Stockpile for use by emergency workers: 31 states
Stockpile for public use, but do not predistribute: six states
Predistribute to public immediately residing around a nuclear power plant: one state
Adopted a position not to use for anyone: four states
Adopted a position not to use for the general public only: five states

The survey covers 37 states which have an Emergency Planning Zone within their jurisdiction.

Overseas, the United Kingdom has stockpiled but not predistributed the drug for public use. Sweden has made the drug available and predistributed it to populations around reactor sites.

Another argument against the predistribution of the drug is that the probability for a reactor accident which would release radioiodine to the environment is very low and that, in any case, previous estimates of the amount of radioiodine released in an accident are too high. The probability issue is beyond the context of this discussion. Concerning the source term (amount of radioiodine released), it is reasonable to conclude that if less radioiodine than previously estimated is released in a reactor accident, the zone in which potassium iodide would be useful would be greatly reduced but would not disappear altogether.

The cost effectiveness of stockpiling potassium iodide has also been raised as a significant issue for concern. A Nuclear Regulatory Commission study indicates that the use of potassium iodide as a thyroid-blocking agent on a large scale may not be cost-effective.[26] This study determined cost-effectiveness from the cost of the drug, the number of thyroid nodules that could be avoided by its use, and the probability of a catastrophic nuclear power plant accident. The study concluded that if the probability of a nuclear power plant accident of the type that releases consequential quantities of radioiodine is one in about 1,400 years with the present number of operating nuclear power reactors, the large scale stockpiling and distribution of potassium iodide would not be cost-effective. Of

course, the cost-effectiveness of other emergency measures (for example, alerting and warning systems) should also be considered for a fair comparison. The probability of an accident influences the cost-effectiveness of all emergency planning measures, including the use of potassium iodide. If the probability of a serious reactor accident were greater, then the cost-effectiveness of stockpiling potassium iodide would be more favorable. Although production, distribution, and stockpiling costs on a national basis may be significant, the procurement of potassium iodide tablets has been estimated to cost about 40 to 75 cents per person dose package. Potassium iodide solution in 1 ounce bottles, containing enough drug for an entire family, may cost less on a per person basis.

Conclusion

In view of the current state of knowledge of radiation risks to the thyroid and the benefits and risks of potassium iodide as a thyroid-blocking agent, no new compelling evidence suggests a need to modify the current F.D.A. recommendations on the use of potassium iodide as a thyroid-blocking agent. The Department of Health and Human Services and the F.D.A. concur with a draft statement of federal policy that incorporates the principle that individual states are responsible for formulating policies concerning the stockpiling and distribution, as well as if and when to use this drug in radiation accidents that release radioiodines to the environment.

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